IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

JANET DAHSE, et al.,

Plaintiffs,

v. Civil Action No. 2:12-cv-02701

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Defendant's Motion for Summary Judgment*)

Pending before the court is defendant C. R. Bard's ("Bard") Motion for Summary Judgment [ECF No. 77]. As set forth below, Bard's Motion for Summary Judgment is **GRANTED IN PART** with respect to the plaintiffs' claims for manufacturing defect, breach of implied warranty, breach of express warranty, and negligent inspection, packaging, marketing, and selling. Bard's Motion for Summary Judgment is **DENIED IN PART** with respect to the plaintiffs' strict liability design defect and failure to warn claims, and the plaintiffs' negligent design and failure to warn claims.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven

MDLs, there are more than 58,000 cases currently pending, approximately 8,000 of which are in the Bard MDL, MDL 2187. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order ("PTO") # 102, No. 2:12-md-2187 [ECF No. 729]. This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Dahse's case was selected as a Wave 1 case by the plaintiffs. PTO # 118, No. 2:12-md-2187 [ECF No. 841].

Ms. Dahse was surgically implanted with the Avaulta Solo Synthetic Support System (the "Avaulta") by Dr. Alisa Berger at the Brazosport Regional Health System in Lake Jackson, Texas. Compl. 4 [ECF No. 1]. As a result of complications allegedly caused by the Avaulta, Ms. Dahse brings the following claims against Bard: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breaches of express and implied warranties; and punitive damages.[1] *Id.* at 5. In the instant motion, Bard moves for partial summary judgment on the grounds that it "is not at fault for the damages alleged by" Ms. Dahse. Mem. Supp. Mot. Summ. J. 1 [ECF No. 78].

[1] Bard also filed a Motion for Partial Summary Judgment on Punitive Damages Claims [ECF No. 63]. That motion is addressed in a separate order.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105

F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases. The choice of law for these pretrial motions depends on whether they concern federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for a dispositive motion, I generally refer to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Dahse did in this case, I consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17,

2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Dahse received the Avaulta implantation surgery in Texas. Thus, the choice-of-law principles of Texas guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of Texas law to the plaintiffs' claims. In tort actions, Texas adheres to the Restatement (Second) of Conflict of Laws (Am. Law Inst. 1975). *Gutierrez v. Collins*, 583 S.W.2d 312, 318 (Tex. 1979). Under section 145 of the Restatement (Second) of Conflict of Laws, the court must apply the law of the state with the most "significant relationship to the occurrence and the parties." Here, Ms. Dahse resides in Texas, and the product was implanted in Texas. Thus, I apply Texas's substantive law to this case.

III. Analysis

Bard argues that it is entitled to partial summary judgment in this case because the plaintiffs' claims lack evidentiary support. The plaintiffs have agreed not to pursue claims for manufacturing defect. *See* Response 3 [ECF No. 126]. Accordingly, Bard's Motion on the plaintiffs' claims for manufacturing defect is **GRANTED.** Below, I apply the summary judgment standard to each remaining claim.

A. Strict Liability

Texas has adopted the doctrine of strict liability for defective products set forth

in section 402A of the Restatement (Second) of Torts ("Restatement"). *See McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787, 789 (Tex. 1967). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement § 402A. "The concept of defect is central to a products liability action brought on a strict tort liability theory, whether the defect be in conscious design, or in the manufacture of the product, or in the marketing of the product." *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 847 (Tex. 1979).

1. Design Defect

In Texas, a plaintiff bringing a design defect claim under strict liability must prove by a preponderance of the evidence that (1) the product was unreasonably dangerous due to a defect, (2) "there was a safer alternative design," and (3) "the defect was a producing cause" of the damages. Tex. Civ. Prac. & Rem. Code Ann. § 82.005; *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009). To determine whether a product is unreasonably dangerous, Texas courts apply a risk-utility test that considers the following factors:

(1) the utility of the product to the user and to the public as a whole

> weighed against the gravity and likelihood of injury from its use;
>
> (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive;
>
> (3) the manufacturer's ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs;
>
> (4) the user's anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and
>
> (5) the expectations of the ordinary consumer.

Am. Tobacco Co. v. Grinnell, 951 S.W.2d 420, 432 (Tex. 1997); *see also Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 256 (Tex. 1999). Whether the product is unreasonably dangerous is generally an issue for the jury. *Timpte Indus.*, 286 S.W.3d at 312; *Am. Tobacco*, 951 S.W.2d at 432.

Bard argues that comment k to section 402A bars the plaintiffs' design defect claims. Comment k exempts certain products from strict liability because they are "unavoidably unsafe."[2] The interpretation and treatment of this exemption varies.

[2] Comment k provides as follows:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate

Some courts have found that comment k categorically bars design defect claims for certain medical products. *See, e.g.*, *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988) (leading case adopting categorical approach). Thus, in these states, comment k is an absolute bar to design defect claims for particular classes of products. Other courts have adopted a case-by-case approach. *See, e.g.*, *Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 308 (Idaho 1987) (leading extant case adopting case-by-case approach). Thus, in these states, whether comment k bars a claim for design defect depends on the particular product at hand.

I reject Bard's contention that Texas's absolute bar for FDA-approved prescription drugs applies here given that the Avaulta is neither FDA-approved nor a prescription drug. *See Lofton v. McNeil Consumer & Speciality Pharm.*, 682 F. Supp. 2d 662, 679 (N.D. Tex. 2010) (refusing to "take a leap not taken by Texas courts" in applying comment k categorically outside the prescription drug context); *see also Carter v. Tap Pharm., Inc.*, No. SA-03-CA-0182, 2004 WL 2550593, at *2 (W.D. Tex. Nov. 2, 2004) ("Under Texas law, all FDA-approved prescription drugs are unavoidably unsafe as a matter of law.").

Bard also argues that the plaintiffs have presented no evidence of a safer alternative design. The plaintiffs, however, note that they have suggested that Bard's Avaulta product could have been designed with larger pore sizes, could have been designed with rounder, thinner arms, or could have been made, in part, with native

---

> consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (1965).

tissue. According to the plaintiffs, these design alternatives would have made the Avaulta a safer product. Bard argues that these are new products, and such products do not demonstrate a "safer alternative design." *See Massa v. Genetech, Inc.*, No. H–11–70, 2012 WL 956192, at *6 (S.D. Tex. Mar. 19, 2002) ("A plaintiff cannot demonstrate the existence of a 'safer alternative design' by pointing to a substantially different product . . . ."). At a minimum, the plaintiffs have established that there is a genuine dispute over whether their suggestions for the Avaulta amount to a safer, alternative design.

Bard presents no other argument on design defect. Thus, Bard has failed to meet its burden under the summary judgment standard of showing the absence of a genuine dispute as to any material fact. *See* Fed. R. Civ. P. 56(a); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970), *superseded on other grounds by Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). Therefore, Bard's Motion on the plaintiffs' claim of strict liability for design defect is **DENIED**.

2. Failure to Warn

Texas, like most jurisdictions, follows the learned intermediary doctrine. *See, e.g.*, *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974) (applying Texas law); *Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 461-66 (Tex. App. 2000); *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex. App. 1998). Under that doctrine, when there is a patient-physician relationship, the manufacturer of a drug or medical device has a duty to warn that extends only to the physician. *See Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010); *Bean*, 965 S.W.2d at 663. The manufacturer

does not have a duty to warn the patient who receives the drug or device. *Pustejovsky*, 623 F.3d at 276.

"In order to recover for a failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) the warning was defective; and (2) the failure to warn was a producing cause of the plaintiff's condition or injury." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (applying Texas law). To prove causation, "the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would have not used or prescribed the product." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (quoting *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 714 (N.D. Tex. 2000)).

Additionally, Bard argues that the plaintiffs' failure to warn claim fails under the learned intermediary doctrine because the plaintiffs cannot prove that a failure to warn caused Ms. Dahse's injuries. In response, the plaintiffs note that Dr. Berger, Ms. Dahse's implanting physician, stated that had she been aware of the extent and manner in which Bard tested the Avaulta, she would not have implanted the Avaulta in Ms. Dahse. Dr. Alisa Berger Dep. 117:10–118:20 [ECF No. 126-1]. The plaintiffs have demonstrated that there is a genuine dispute over whether Dr. Berger would have implanted the plaintiff with the Align had she been as fully informed as the plaintiffs have suggested. Accordingly, Bard's Motion on the plaintiffs' strict liability failure to warn claims is **DENIED**.

B. Negligence

When the plaintiffs' claims for strict liability fail, then so too should the negligence claims. *See Gerber v. Hoffmann-La Roche Inc.*, 392 F. Supp. 2d 907, 923 (S.D. Tex. 2005) (holding that where summary judgment was proper as to strict liability claims for failure to warn, design defect, and manufacturing defect, then those same claims premised on negligence must also fail). Accordingly, based on the preceding rulings, Bard's motion for summary judgment is **GRANTED** with respect to the plaintiffs' negligent manufacturing defect claim, and is **DENIED** with respect to the plaintiffs' negligent design claim and negligent failure to warn claim.

Bard contends that the plaintiffs' claims for negligent inspection, packaging, marketing, and selling of the Avaulta fail for lack of evidence. The plaintiffs, in response, argue that there is ample evidence that demonstrates Bard breached a duty to the plaintiffs and that there was resulting harm from this breach. Response 9 [ECF No. 126]. The plaintiffs state that Bard was negligent in failing to include adequate warnings, failing to include appropriate instructions for use, exaggerating the benefits of the Avaulta, and marketing and selling the Avaulta without adequate testing. *Id.* at 10. However, apart from reciting allegations that form the plaintiffs' failure to warn and design defect claims, the plaintiffs do not offer any support that Bard breached a legal duty that caused the plaintiffs' injuries in their "inspection, marketing, labeling, packaging, or selling" of the Align. Accordingly, Bard's Motion on these points is **GRANTED.**

C. Express and Implied Warranties

To recover for the breach of an express or implied warranty, Texas law requires that a plaintiff provide notice to the seller before filing suit. Section 2.607(c)(1) of the Texas Business & Commerce Code mandates that "the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." Tex. Bus. & Com. Code Ann. § 2.607; *see also Ackermann v. Wyeth Pharm.*, 471 F. Supp. 2d 739, 745 (E.D. Tex. 2006) *aff'd*, 526 F.3d 203 (5th Cir. 2008) ("[T]he Court agrees that to maintain the claim for breach of warranty, notice was required."); *Wilcox v. Hillcrest Mem'l Park*, 696 S.W.2d 423, 424-25 (Tex. App. 1985) ("[S]ection 2.607(c)(1) requires that a buyer notify any seller . . . of the product's alleged defect within a reasonable time of discovering the defect and that failure to do so bars the buyer from any remedy for breach of warranty under the Texas Business & Commerce Code."). The rule applies to manufacturers as well as sellers. *See U.S. Tire-Tech, Inc. v. Boeran, B.V.*, 110 S.W.3d 194, 199 (Tex. App. 2003) ("[U]nder section 2.607(c)(1), a buyer is required to give notice of an alleged breach of warranty to a remote manufacturer.").

Here, Ms. Dahse has presented no evidence of pre-suit notice. Accordingly, Bard's Motion on the plaintiffs' warranty claims is **GRANTED**.

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that Bard's Motion [ECF No. 67] is **GRANTED IN PART** with respect to the plaintiffs' claims for manufacturing defect, breach of implied warranty, breach of express warranty, and negligent

inspection, packaging, marketing, and selling. Bard's Motion is **DENIED IN PART** with respect to the plaintiffs' strict liability design defect and failure to warn claims, and the plaintiffs' negligent design and failure to warn claims.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 7, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE